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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/768,183	01/23/2001	Jeno Gyuris	GPCI-P03-109	1943
28120	7590	11/04/2003	EXAMINER	
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			YU, MISOOK	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 11/04/2003				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/768,183

Applicant(s)

GYURIS ET AL.

Examiner

MISOOK YU, Ph.D.

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 28-33,54-88 and 93-104 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 28-33,54-88 and 93-104 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 21.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

### DETAILED ACTION

Amendment (Paper No. 20) filed on 08-21-2003 is entered.

Claims 28-33, 54-88, and 93-104 are pending and examined on merits.

#### ***Claim Rejections - 35 USC § 112***

Claims 28-33, 54-89, and 93-104 are also rejected for reason of record under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicant argues this time that “increased biological activity” means something other than previously argued, for example, at 2<sup>nd</sup> paragraph of page 14 of the amendment filed on 07-05-2002 (Paper No. 11), where it says **“The Office Action seem to have misinterpreted the claimed invention which is partly directed to the discovery that serum albumin serve as a ‘protein carrier’ to a heterologous polypeptide inserted herein, and confers the inserted heterologous polypeptide an increased lifetime (half-life), and thus increased observed biological activity relative to the uninserted heterologous polypeptide (for example, see paragraph bridging at page 5 and 6).**

The prosecution history shows that applicant argued that the full scope of claims are enabled because the role of SA is a carrier and the Office’s rejection based on unpredictability in protein chemistry art does not apply to the instant invention. However, applicant appears to argue “increased biological activity means 1000-fold

Art Unit: 1642

more activity of EC binding peptide as disclosed in the specification. This finding appears to be exception, not expected to happen for every peptide inserted in SA according to the argument presented in the instant amendment, and the disclosure in the specification, and/or the teachings of art. This rejection is maintained for reason of record provided in the three previous Office actions because the specification does not teach how to make such construct that would increase 1000-fold more activity: if applicant maintains the claimed invention is a product with 1000-fold more activity of the inserted peptide, then written description rejection withdrawn in the Office Action mailed on 09-24-2003 would be reinstated. Applicant has argued several inconsistent interpretations of the scope and contents of the claims and each different claim interpretation gives rise to different rejections. It would be helpful if applicant states unequivocally what is the true invention claimed in the instant application before proceeding further.

***Claim Rejections - 35 USC § 102***

Claims 28, 54, 55-77, 93-104 remain rejected under 35 U.S.C. 102(b) as being anticipated by WO 95/30759 (Publication date Nov. 6, 1995, IDS AB filed on July 5, 2002, Paper No. 12) as evidenced by Zetter (1998, Annu Rev Med. Vol. 49, pages 407-24, abstract only) and by Fixe et al, Cytokine 1998 Jan;10(1):32-7.

Applicant argues that EC binding peptides inserted in SA exhibits 1000-fold more activity and the art does not show this dramatic increase as shown at page 44 of the specification. However, these arguments are not persuasive because the claims are not limited to the specific structure. The prosecution history indicates that applicant

argued that increased plasma half-life stability is increased biological activity. See above bold-faced direct quotation of applicant's argument. Until this matter is settled, the Office maintains this rejection.

***Claim Rejections - 35 USC § 103***

Claims 29-33 remain rejected under **35 U.S.C. 103(a)** as being unpatentable over WO 95/30759 (Publication date Nov. 6, 1995, IDS AB filed on July 5, 2002, Paper No. 13) as applied to claims 28, 54, and 55 above, and further in view of admission in the specification at pages 16-22.

Applicant argues WO 95/30759 is not art but this argument is not persuasive for reasons given in 102 (b) rejection above.

Claims 80-84 are rejected under **35 U.S.C. 103(a)** as being unpatentable over WO 95/30759 (Publication date Nov. 6, 1995, IDS AB filed on July 5, 2002, Paper No. 13) as applied to claims 28, 54, and 54 above, and further in view of Cardarelli et al, J Biol Chem 1992 Nov 15;267(32):23159-64.

Applicant argues WO 95/30759 is not art but this argument is not persuasive for reasons given above.

Claims 85-88 are rejected under **35 U.S.C. 103(a)** as being unpatentable over WO 95/30759 (AB of IDS, Paper No. 14, publication date: 11/16/1995) as applied to claims 28 above in view of Carter et al (1994, Advances in Protein Chemistry, vol. 45, pages 153-203, IDS AE filed on July 5, 2002, Paper No. 12). The claims are interpreted as drawn to nucleic acid encoding chimeric polypeptide comprising serum albumin with

Art Unit: 1642

a useful heterologous peptide inserted into various recited serum albumin cysteine loops.

Applicant argues WO 95/30759 is not art but this argument is not persuasive for reasons given above.

### ***Double Patenting***

Claims 28-33, 54-84, 93-104 remain provisionally rejected for reason of record under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-33, and 49-91 of copending Application No. 09/619,285. Applicant states TD will be filed when one of the application goes to issue.

### ***Conclusion***

No claim is allowed.


**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MISOOK YU, Ph.D. whose telephone number is 703-308-2454. The examiner can normally be reached on 8 A.M. to 5:30 P.M., every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony C Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
**MARY E. MOSHER**  
**PRIMARY EXAMINER**  
**GROUP 1600** 1600

Misook Yu

November 3, 2003